UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHARLIE UTTS and CIARA UTTS, Plaintiffs, -v- BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC., Defendants.	:	16cv5668(DLC) OPINION AND ORDER

APPEARENCES:

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DENISE COTE, District Judge:

Plaintiffs Charlie and Ciara Utts bring this product liability lawsuit against defendants Bristol-Myers Squibb Company ("BMS") and Pfizer Inc. ("Pfizer"), alleging that Mr. Utts suffered severe internal bleeding caused by taking Eliquis, a prescription drug manufactured, marketed, and distributed by the defendants. The defendants have moved to dismiss the

complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, the defendants' motion is largely granted, with leave to amend most of the dismissed claims.

BACKGROUND

The following facts are drawn from the complaint and documents integral to it, including the Eliquis label approved by the Federal Drug Administration ("FDA"). The facts are construed in favor of the plaintiffs. See Keiler v. Harlequin Enters. Ltd., 751 F.3d 64, 68 (2d Cir. 2014).

Plaintiffs Charlie and Ciara Utts are both residents of California. Mr. Utts was diagnosed with atrial fibrillation[1] some time before July 2014 and prescribed Eliquis by his doctor. Mr. Utts suffered severe internal bleeding after taking Eliquis.

Eliquis -- the brand name of the prescription medicine apixaban -- is an anticoagulant, blood-thinning medication used to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. Unlike other anticoagulant medications such as warfarin, Eliquis does not have a known antidote or reversal agent. It does, however, have

[1] Atrial fibrillation is a common arrhythmia (i.e., abnormal heart beat) that causes blood clots to form in the heart. Individuals with atrial fibrillation are at a high risk of stroke and use medications such as Eliquis to reduce the risk of stroke.

certain marked advantages over other anticoagulant medications. For example, Eliquis does not require periodic blood testing, nor does it impose dietary restrictions on its users.

I. FDA Approval of Eliquis

The FDA approved Eliquis for sale and marketing in the United States in 2012. Pursuant to federal law, all applications for FDA approval of new drugs must include a description of the clinical investigations of the drug, including an analysis of each clinical pharmacology study of the drug and each controlled clinical study pertinent to a proposed use of the drug. See 21 C.F.R. § 314.50(d)(5). In accordance with this requirement, the defendants submitted the results of the international clinical trials known as ARISTOTLE. The plaintiffs allege several deficiencies with the ARISTOTLE study, including the defendants' use of "incompetent and untrustworthy agents in China to conduct the ARISTOTLE study." The plaintiffs further contend that the defendants concealed several side effects experienced by study participants.[2]

While the defendants' application was pending before the FDA, Dr. Thomas Marcinak, an FDA employee appointed to review

[2] The allegedly concealed side effects include: (1) an unreported death; (2) loss of subjects to follow-up; (3) major dispensing errors including indicating that certain subjects were receiving Eliquis when they were not; (4) poor overall quality control; and (5) changing and falsifying records, including records disappearing just before the FDA conducted a site visit.

the Eliquis application, recommended that the proposed Eliquis label discuss the quality control problems associated with the ARISTOTLE study. In response to concerns about the rigor of the ARISTOTLE study, the defendants stated that they were submitting additional data to the FDA for its consideration.

II. The Eliquis Label

At the time Mr. Utts was prescribed Eliquis, the label contained several warnings about the risk of bleeding. For example, the "Warnings and Precautions" section of the label provides, under a subheading entitled "Bleeding," that:

> ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding. . . . There is no established way to reverse the anticoagulant effect of apixaban, which can be expected to persist for about 24 hours after the last dose, i.e., for about two half-lives. A specific antidote for ELIQUIS is not available.

The "Adverse Reactions" section further provides that "[t]he most serious adverse reactions reported with ELIQUIS were related to bleeding," while the "Overdosage" section noted that "[t]here is no antidote to ELIQUIS. Overdose of ELIQUIS increases the risk of bleeding." Finally, the "Patient Counseling Information" section instructs physicians to inform their patients that "it might take longer than usual for bleeding to stop," and that "they may bruise or bleed more easily when treated with ELIQUIS."

The label also instructs physicians to "[a]dvise patients about how to recognize bleeding or symptoms of hypovolemia and of the urgent need to report any unusual bleeding to their physician."

The Eliquis label specifically references the ARISTOTLE study. It provides that "[t]he safety of ELIQUIS was evaluated in the ARISTOTLE and AVERROES studies," and that the "most common reason for treatment discontinuation in both studies was for bleeding-related adverse reactions." It notes that "in ARISTOTLE this occurred in 1.7% and 2.5% of patients treated with ELIQUIS and warfarin, respectively, and in AVERROES, in 1.5% and 1.3% on ELIQUIS and aspirin, respectively."

Finally, the Eliquis Medication Guide -- a paper insert in all prescription medicine packages -- instructs patients that "ELIQUIS can cause bleeding which can be serious and rarely may lead to death. This is because ELIQUIS is a blood thinner medicine that reduces blood clotting." (Emphasis in original.)

III. Procedural History

The plaintiffs filed their complaint on July 15, 2016. The complaint asserts twelve causes of action against the defendants: (1) product liability - design defect; (2) product liability - manufacturing defect; (3) product liability -

failure to warn; (4) product liability - strict liability; (5) negligence; (6) breach of express warranty; (7) breach of implied warranties; (8) fraudulent concealment; (9) negligent misrepresentation; (10) fraud; (11) violation of consumer protection laws; and (12) loss of consortium on behalf of Mrs. Utts.

On October 5, the defendants filed a motion to dismiss under Rules 12(b)(6) and 9(b). On October 13, the defendants moved the Judicial Panel on Multidistrict Litigation ("JPML") to transfer and coordinate 34 actions pending in 13 different district courts, including the instant action, pursuant to 28 U.S.C. § 1407. On October 21, the parties in the instant action filed a letter requesting that the Honorable Lewis A. Kaplan stay all proceedings pending resolution of the JPML petition. The request to enter a stay was denied on October 28.

On November 21, the case was reassigned to this Court as related to 16 other product liability cases concerning the medication Eliquis that have been filed in this district.[3] That same day, this Court issued an Order instructing the parties in this case and all related

[3] The parties had requested that litigation be stayed in each of this district's actions until the JPML rules on the defendants' motion to transfer. As a result, only the motion to dismiss filed in the instant action has been fully briefed.

actions to confer and identify one motion that is appropriate for early resolution. The November 21 Order also explained that the initiation of discovery would turn on whether or not the Court denies the selected motion to dismiss. On December 2, the parties identified the present motion to dismiss as the one motion appropriate for early resolution. The motion to dismiss became fully submitted on December 5.

DISCUSSION

When deciding a motion to dismiss, a court must "accept all allegations in the complaint as true and draw all inferences in the non-moving party's favor." LaFaro v. New York Cardiothoracic Grp., PLLC, 570 F.3d 471, 475 (2d Cir. 2009) (citation omitted). "To survive a motion to dismiss under Rule 12(b)(6), a complaint must allege sufficient facts which, taken as true, state a plausible claim for relief." Keiler, 751 F.3d at 68; Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) ("[A] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." (citation omitted)). A claim has facial plausibility when "the factual content" of the complaint "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Tongue v. Sanofi, 816 F.3d 199, 209 (2d Cir. 2016) (citation omitted). "Where a complaint pleads facts

that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Iqbal, 556 U.S. at 678 (citation omitted). In sum, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (citation omitted).

To satisfy the requirements of Rule 9(b), the complaint must: (1) detail the events giving rise to the fraud, such as the statement/omission that is alleged to be fraudulent, the identity of the speaker, the location of the fraud, and the reason the statement is fraudulent; and (2) allege facts "that give rise to a strong inference of fraudulent intent." Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC, 797 F.3d 160, 171 (2d Cir. 2015) (citation omitted).

In deciding a motion to dismiss, the court considers "any written instrument attached to the complaint as an exhibit or any statements or documents incorporated in it by reference," Stratte-McClure v. Morgan Stanley, 776 F.3d 94, 100 (2d Cir. 2015) (citation omitted), as well as "documents upon which the complaint relies and which are integral to the complaint." Subaru Distribs. Corp. v. Subaru of Am., Inc., 425 F.3d 119, 122

(2d Cir. 2005). The Eliquis label and package insert are integral to the complaint.

I. Choice of Law

A district court, sitting in diversity, applies the choice of law rules of the forum state -- in this case, New York law. Alphonse Hotel Corp. v. Tran, 828 F.3d 146, 152 (2d Cir. 2016). Under New York choice of law rules, "the first step in any case presenting a potential choice of law issue is to determine whether there is an actual conflict between the laws of the jurisdictions involved." Licci ex rel. Licci v. Lebanese Canadian Bank, SAL, 672 F.3d 155, 157 (2d Cir. 2012) (citation omitted). A choice of law analysis need not be performed unless there is an actual conflict between the applicable rules of relevant jurisdictions. Id. If no actual conflict exists, and if New York is among the relevant jurisdictions, the court may simply apply New York law. Id.

Choice of law analysis is conducted on a claim-by-claim basis. See Fieger v. Pitney Bowes Credit Corp., 251 F.3d 386, 397 n.1 (2d Cir. 2001) (discussing the doctrine of dépeçage). But, "where the parties agree that a certain jurisdiction's law controls, this is sufficient to establish choice of law." Alphonse, 828 F.3d at 152 (citation omitted); see also Krumme v. WestPoint Stevens Inc., 238 F.3d 133, 138 (2d Cir. 2000).

The parties have not performed the first step under New York's choice of law analysis, which is to identify whether a true conflict exists between California and New York law. The defendants, for example, immediately proceed to conduct a choice of law analysis for the plaintiffs' contract and tort claims, apparently on the assumption that there is a conflict between New York and California law on each cause of action. Based on their analysis, the defendants conclude that California law governs the present motion in its entirety.

The plaintiffs, by contrast, simply assert that "New York and California agree on virtually every aspect of applicable law" save for design defect claims, but that a "full" choice of law analysis is "premature at this stage" because "there has been no discovery as to where Mr. Utts ingested Eliquis" or where he may have been treated. The plaintiffs proceed to analyze their claims under both California and New York law.

Since Mr. Utts presumably knows where he ingested Eliquis, it is not premature to conduct a choice of law analysis. Indeed, it is essential to do so to address the pending motion. Since the complaint recites that Mr. Utts is a citizen and resident of California, and plaintiffs rely on California law in opposing this motion, for purposes of this Opinion it is assumed that the parties have agreed that California law controls.

II. FDA Approval Process

In their motion to dismiss the defendants assert that several of plaintiffs' claims are preempted by federal law. Before describing the law of preemption, it is helpful to describe in general terms the regulatory scheme that governed the FDA approval of Eliquis.[4]

The Food, Drug, and Cosmetic Act of 1938 ("FDCA") is a federal law that regulates the manufacture, use, or sale of drugs. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 196 (2005). Under the FDCA, a drugmaker must submit research data to the FDA at two general stages of new-drug development. First, a drugmaker must gain authorization to conduct clinical trials (tests on humans) by submitting an investigational new drug application ("IND"). See 21 U.S.C. § 355(i); 21 C.F.R. § 312.20-312.21. The IND must describe "preclinical tests (including tests on animals) of [the] drug adequate to justify the proposed clinical testing." 21 U.S.C. § 355(i)(1)(A); see 21 C.F.R. §§ 312.23(a)(5) and (a)(8) (specifying necessary information from preclinical tests).

[4] This Opinion is analyzed under FDCA laws and regulations in existence as of December 5, 2016, when the present motion became fully submitted. On December 13, 2016, Congress passed the 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033. The parties have not suggested that anything in this new act affects the law governing the present motion.

Second, to obtain authorization to market a new drug, a drugmaker must submit a new drug application ("NDA"). Such applications must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1). To obtain approval under the FDCA, the manufacturer must demonstrate to the FDA that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling." Id. § 355(d). The manufacturer must also prove the drug's effectiveness by "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." Id. Drug manufacturers must also submit proposed labeling, with annotations, to be used with the drug. Id. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i). The FDA's premarket approval of an NDA includes the approval of the exact text in the proposed label. See 21 U.S.C. § 355; 21 C.F.R. § 314.105(b).

After approval, drug manufacturers have ongoing obligations to monitor a drug's risks and to report adverse drug responses to the FDA. See 21 C.F.R. §§ 314.80, 314.81, 314.98. The FDCA also prohibits the manufacture or distribution of any drug, whether previously approved for sale by the FDA or not, that is misbranded. 21 U.S.C. § 352. A drug is misbranded if, inter

alia, it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." Id. § 352(j). Where the FDA had previously approved a drug for sale, the misbranding prohibition applies when there is significant new scientific evidence demonstrating that the drug is unsafe. See Mutual Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466, 2484 (2013) (Sotomayor, J., dissenting).

The FDCA prohibits a manufacturer from making any major changes to the "qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved NDA." 21 C.F.R. § 314.70(b)(2)(i). Moderate changes must be reported to the FDA "at least 30 days prior to distribution of the drug product made using the change," id. § 314.70(c) (emphasis added), while minor changes need only be reported in an annual report to the FDA.[5] Id. § 314.70(d)(3).

In addition to regulating changes to the drug formulation, federal law regulates changes to pharmaceutical labels.

[5] Minor changes that do not require prior notification to and/or approval from the FDA include "[t]he deletion or reduction of an ingredient intended to affect only the color of the drug product" and "[a] change in the size and/or shape of a container containing the same number of dosage units." 21 C.F.R. §§ 314.70(d)(2)(ii), (iv).

Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application.

A manufacturer may, however, make certain changes to its label without prior agency approval through the "changes being effected" ("CBE") regulation. The CBE regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" for which there is sufficient "evidence of a causal association," or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval. Id. §§ 314.70(c)(6)(iii)(A), (C).

Labeling changes pursuant to the CBE regulation may only be made on the basis of "newly acquired information." Id. § 314.70(c)(6)(iii). "Newly acquired information" is defined as:

> [D]ata, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

Id. § 314.3(b). Information previously known to the manufacturer, but not submitted to the FDA, may constitute "newly acquired information," provided that the information

meets the other CBE requirements. See Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49606 (2008). The FDA retains the authority to reject labeling changes made pursuant to the CBE regulations. Wyeth v. Levine, 555 U.S. 555, 571 (2009).

III. Federal Preemption

The defendants argue that federal law preempts many of the plaintiffs' claims, including all of the product liability claims. The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl.2. "A fundamental principle of the Constitution is that Congress has the power to preempt state law." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000). State law is preempted by federal law when: (1) Congress intends federal law to "occupy the field," or (2) where state law conflicts with a federal statute. Id. (citation omitted).

Conflict preemption exists "where it is impossible for a private party to comply with both state and federal law." Id. "Impossibility pre-emption is a demanding defense." Wyeth, 555 U.S. at 573. Courts must "start with the assumption that the historic police powers of the States were not to be superseded

by the Federal Act unless that was the clear and manifest purpose of Congress." Id. at 565 (citation omitted).

In a recent trilogy of opinions, the Supreme Court addressed the issue of conflict preemption in the context of state product liability claims against drug manufacturers. The first opinion, Wyeth, 555 U.S. 555, analyzed whether a patient's state law claim for inadequate warning brought against a brand name drug manufacturer was preempted by federal law. The other two opinions -- PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011), and Bartlett, 133 S. Ct. 2466 -- addressed issues of preemption as they pertain to generic drug manufacturers. Mensing addressed a state law failure to warn claim. Bartlett analyzed a state law design defect claim. As discussed below, this case law, read holistically, indicates that federal law preempts all pre-FDA approval failure to warn and design defect claims for branded prescription medication.

A. Wyeth v. Levine

In Wyeth, the Supreme Court held that federal law did not preempt a patient's state law failure to warn claim brought against a brand name drug manufacturer. In Wyeth, the plaintiff received in 2000 an injection of Phenergan, a brand name drug used to treat nausea. The drug came in contact with the plaintiff's artery, causing gangrene to spread throughout her arm and resulting in the amputation of the patient's arm. The

plaintiff sued the drug manufacturer, claiming that the labeling was defective because it failed adequately to warn of the dangers of administering the drug intravenously using an IV-push, rather than IV-drip, method. The FDA had approved Wyeth's NDA in 1955, over forty years before the plaintiff was injured. There had been at least twenty reports of amputations similar to the plaintiff's since the 1960s, but no evidence that Wyeth had paid "more than passing attention to the question whether to warn against IV-push administration" of the drug. Wyeth, 555 U.S. at 561-63.

In finding that the plaintiff's state law claims were not preempted, the Court focused exclusively on how the CBE regulation permits -- and even requires -- drug manufacturers to maintain and update their labeling with new safety information as it becomes available. See id. at 568-73. According to the Court, "the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." Id. at 570-71. Thus, "when the risk of gangrene from IV-push injection of Phenergan became apparent," the manufacturer in Wyeth had a "duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval." Id. at 571. Accordingly,

"absent clear evidence that the FDA would not have approved a change to Phenergan's label," the Court would "not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements."[6] Id.; Cf. Medtronic, Inc. v. Lohr, 518 U.S. 470, 500 (1996) (providing, in the context of the Medical Device Amendments of 1976, which contains an express preemption provision, that "pre-emption occur[s] only where a particular state requirement threatens to interfere with a specific federal interest," and that state requirements "of general applicability" are not preempted except where they have "the effect of establishing a substantive requirement for a specific device," that relates "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" (citation omitted)).

The Court's conclusion was premised in part on its understanding of the FDA's "complementary" role in regulating drug safety and efficacy. See id. at 578. As

[6] The plaintiffs misinterpret the "clear evidence" standard set forth in Wyeth. The plaintiffs argue that preemption can be granted only following discovery that shows "there is 'clear evidence' that the FDA would have rejected the label change." But as the Supreme Court again explained in Mensing, only after a court has found that a manufacturer possessed "newly acquired information" to support label changes must a manufacturer demonstrate by "clear evidence" that such proposed changes would nevertheless have been rejected. Mensing, 564 U.S. at 624 n.8. Accordingly, in the absence of a plausible allegation that the manufacturer had "newly acquired information," it is appropriate to dismiss a claim under Rule 12(b)(6) as preempted.

the Court explained, the FDCA did not "establish[] both a floor and a ceiling for drug regulation."[7] Id. at 573. After all, the FDA has "limited resources to monitor the 11,000 drugs on the market" after the drugs receive approval. Id. at 578. State tort law offers "an additional, and important, layer of consumer protection that complements FDA regulation" by helping to uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. Id. at 579. "If Congress thought state-law suits posed an obstacle to its objectives," the Court reasoned, "it surely would have enacted an express pre-emption provision at some

[7] In so finding, the Court declined to defer to the FDA's conclusion of preemption in the preamble to the 2006 regulation governing the content and format of prescription drug labels. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (2006). In the preamble to the 2006 regulation, the FDA declared that the FDCA establishes "both a 'floor' and a 'ceiling,'" such that "FDA approval of labeling . . . preempts conflicting or contrary State law." Id. at 3934-35. It further stated that certain state-law actions, such as those involving failure to warn claims, "threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs." Id. at 3935. The Court, however, found the preamble to be "at odds with what evidence we have of Congress' purposes, and it reverses the FDA's own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence." Wyeth, 555 U.S. at 577. The Court therefore held that the FDA's recent pronouncement of preemption did not merit any deference. Id. at 574-81.

point during the FDCA's 70-year history." Id. at 574. "Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Id. at 575.

In sum, the Court in Wyeth focused exclusively on what a drug manufacturer could do post-FDA approval to enhance the warnings of serious risks in the labeling of its product. Wyeth did not address whether a state law failure to warn claim addressed to the NDA process was preempted.

B. PLIVA, Inc. v. Mensing

In Mensing, the Court held that state law failure to warn claims against generic drug manufacturers were preempted by federal law. The claim concerned the drug metoclopramide, which the FDA first approved in 1980 under the brand name Reglan for treatment of digestive tract problems. Five years later, generic manufacturers began producing metoclopramide. Evidence began to accumulate that long-term use of the drug could cause a severe neurological disorder in up to 29% of patients. Mensing, 564 U.S. at 609. The plaintiffs, who were prescribed the drug in 2001 and 2002, and were administered the generic version, developed the disorder. Id. at 610.

The Court's analysis focused on the different labeling duties for brand-name and generic drug manufacturers. Id. at 613. Whereas a brand name drug manufacturer seeking an NDA is responsible for the accuracy and adequacy of its label, see, e.g., 21 U.S.C. §§ 355(b)(1), (d); Wyeth, 555 U.S. at 570-71, a manufacturer seeking generic drug approval "is responsible for ensuring that its warning label is the same as the brand name's." Mensing, 564 U.S. at 613 (citation omitted). This "sameness" requirement extends into the post-approval phase. In fact, federal law "demand[s] that generic drug labels be the same at all times as the corresponding brand-name drug labels." Id. at 618 (citing 21 C.F.R. § 314.150(b)(10)). Thus, while brand name drug manufacturers may use the CBE process to unilaterally strengthen their warning labels, generic drug manufactures may not; they may only change their labels "to match an updated brand-name label or to follow the FDA's instructions." Id. at 614. The Court concluded that when "the 'ordinary meaning' of federal law blocks a private party from independently accomplishing what state law requires, that party has established pre-emption." Id. at 623.

The Court in Mensing also considered whether conflict preemption should take into account possible actions that, in retrospect, the FDA and brand-name manufacturer could have taken. Id. at 620. As the FDA had noted in its amicus brief,

while generic drug manufacturers cannot update their labels pursuant to the CBE regulation, they can still propose stronger warning labels to the agency if they believe such warnings are needed; if the FDA agrees that a label change is necessary, it can work with a brand name drug manufacturer to create a new label for both the brand name and generic drug. Id. at 616. The plaintiffs, in turn, argued that if the generic manufacturers had asked the FDA for help in changing the corresponding brand name label, they might eventually have been able to accomplish under federal law what state law required. The Court dismissed this argument as far too attenuated:

> [P]re-emption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties. . . . [We] hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.

Id. at 623-24 (emphasis supplied). In sum, the Court refused to force generic manufacturers to engage in a "Mouse Trap game" that would eventually lead to a better label on a generic drug. Id. at 619.

C. Mutual Pharmaceutical Co., Inc. v. Bartlett

In Bartlett, the Supreme Court held that a plaintiff's state law design defect claim against the manufacturer of a

generic drug was preempted by federal law. The drug at issue was sulindac. In 1978, the FDA approved this nonsteroidal anti-inflammatory pain reliever under the brand name Clinoril. Bartlett, 133 S. Ct. at 2471. When the patent expired, generic sulindac was approved as well. Id. In a small number of patients, use of this class of drugs can cause serious side effects. In 2004, the plaintiff was dispensed the generic form and had a horrifying reaction to it. She is now severely disfigured and disabled. Id. at 2472.

Relying on Mensing, the Court reasoned that a generic drug manufacturer is prohibited by federal regulation from independently changing the drug's design. As the Court explained, "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." Id. at 2475 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v) and (8)(B); 21 C.F.R. § 320.1(c)). If the generic manufacturer were to change the composition of the generic drug, "the altered chemical would be a new drug that would require its own NDA to be marketed in interstate commerce." Id.

The Court in Bartlett also rejected a "stop-selling" rationale, wherein a manufacturer can escape the impossibility of complying with both its federal and state law duties by

choosing not to manufacturer a drug at all. Id. at 2477-78. As the Court explained,

> Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless.

Id. at 2477 (citation omitted).

D. The Implications of the Supreme Court's Decisions for State Law Claims Addressed to Brand Name Drugs

In addressing failure to warn and design defect claims in the context of generic drugs, the Court found a conflict between state and federal law requirements that rendered compliance with both laws impossible. Where generic drug manufacturers did not have the authority to unilaterally change either the drug's design or the label's warning, federal law preempted the state law claims.

This same lack of authority to alter a drug's design or a label's warnings exists for brand name drug manufacturers at the time the NDA process concludes. They have received approval only for that formulation and that label that survive the NDA process. Thereafter, however, depending on the significance of the change to the drug's design or the type of change in a label, federal regulations permit manufacturers to unilaterally alter the design and label. Indeed, they have a duty to act.

Because manufacturers have greater access to information about their drugs than the FDA, and the FDA has limited resources, manufacturers retain the responsibility for the safety of their products after they receive FDA clearance for their sale and marketing. Among other things, they have an ongoing obligation to monitor a drug's risks and to report adverse responses. See Bartlett, 133 S Ct. at 2484 (Sotomayor, J., dissenting). As the Supreme Court has surmised, Congress has not provided a federal remedy for consumers harmed by unsafe or ineffective drugs because it has "recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." Wyeth, 555 U.S. at 574.

Accordingly, depending on the nature of the plaintiff's failure to warn and design defect claim for a branded drug, the claim may be preempted. If the claim addresses newly acquired information and addresses a design or labeling change that a manufacturer may unilaterally make without FDA approval, then there may be no preemption of the state law claim. On the other hand, as the Sixth Circuit recently held, a "post-approval design defect claim is clearly preempted by federal law" where FDA regulations prohibit a change of the type implicated by the claim. Yates v. Ortho-McNeil-Janssen Pharm., Inc., 808 F.3d 281, 298 (6th Cir. 2015). Similarly, as the First Circuit has

held, a complaint alleging a labeling deficiency based on information "plainly known to the FDA prior to approving the label" and not information that could be corrected using the CBE regulation, is preempted. In re Celexa & Lexapro Mktg. & Sales Practices Litig., 779 F.3d 34, 43 (1st Cir. 2015).

IV. California Product Liability

California recognizes three theories of product liability: failure to warn, design defect, and manufacturing defect. The complaint asserts these three theories under both strict liability and negligence.

A. Failure to Warn

Failure to warn arises where a manufacturer has issued no warnings or has failed to adequately warn of dangers posed by its product. See Anderson v. Owens-Corning Fiberglas Corp., 53 Cal. 3d 987, 996 (1991). Under California law, a prescription drug manufacturer is strictly liable if it failed to "adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." Carlin v. Superior Court, 13 Cal. 4th 1104, 1112 (1996) (emphasis supplied). Failure to warn based on a negligence theory "requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care,

i.e., what a reasonably prudent manufacturer would have known and warned about." Anderson, 53 Cal. 3d at 1002.

Under California law, application of the failure to warn theory to pharmaceuticals requires the court to determine:

> whether available evidence established a causal link between an alleged side effect and a prescription drug, whether any warning should have been given, and, if so, whether the warning was adequate. These are issues of fact involving, inter alia, questions concerning the state of the art, i.e., what was known or reasonably knowable by the application of scientific and medical knowledge available at the time of manufacture and distribution of the prescription drug. They also necessarily involve questions concerning whether the risk, in light of accepted scientific norms, was more than merely speculative or conjectural, or so remote and insignificant as to be negligible.

Carlin, 13 Cal. 4th at 1116.

As the California Supreme Court has acknowledged, in the failure-to-warn context, strict liability is, to some extent, "a hybrid of traditional strict liability and negligence doctrine" since "the knowledge or knowability requirement for failure to warn infuses some negligence concepts into strict liability cases." Id. at 1111. The knowledge or knowability requirement holds a drug manufacturer to the standard of "knowledge and skill of an expert in the field," and further obligates the manufacturer "to keep abreast of any scientific discoveries" and to "know the results of all such advances." Id. at 1113 n.3. The manufacturer's knowledge "must exist at the time of

distribution." Id. "[S]ubsequently developed scientific data [is not] controlling." Id. In sum, the primary difference between a failure to warn action premised on strict liability and a failure to warn action sounding in negligence is that strict liability "is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct." Id. at 1112.

Even where a risk is "known" or "knowable" at the time of distribution, under California law, a manufacturer "may not be held liable for failing to give a warning it has been expressly precluded by the FDA from giving." Id. at 1115 n.4. Thus, if the manufacturer disclosed to the FDA "state-of-the-art scientific data concerning the alleged risk" and the FDA determined, after its review, "that the pharmaceutical manufacturer was not permitted to warn -- e.g., because the data was inconclusive or the risk was too speculative to justify a warning," then the manufacturer could not be held strictly liable for failure to warn. Id. at 1115. "[T]he FDA's conclusion that there was, in effect, no 'known risk' is controlling."[8] Id.

[8] While the Carlin court refused to find federal preemption of all common law tort remedies to failure to warn, it did acknowledge that FDA regulations were relevant. Carlin, 13 Cal. 4th at 1114.

California also follows the learned intermediary doctrine, which provides that "in the case of prescription drugs, the duty to warn runs to the physician, not to the patient." Id. at 1116. Therefore, a manufacturer discharges its duty to warn if it provides adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient. Finally, "a pharmaceutical manufacturer may not be required to provide warning of a risk known to the medical community." Id.

1. The Plaintiffs' Failure to Warn Claims Appear to Be Preempted.

The defendants move to dismiss the failure to warn claims on the grounds that they are preempted and that, in any event, the warnings on the Eliquis label are adequate as a matter of law. The complaint asserts that the label approved when Eliquis "was first marketed" and at the time the plaintiff used the drug did not contain adequate warnings. The complaint identifies fourteen different warnings that the Eliquis label or "prescribing information" failed to give. For example, it asserts that the defendants failed to disclose that there is "no drug, agent or means to reverse the anticoagulation effects of Eliquis" in the Warnings section of the label. It further asserts that the label failed to include a boxed or bolded warning advising of serious bleeding events associated with

Eliquis. Finally, the complaint relies heavily on the conduct and results of the ARISTOTLE study, which the defendants presented to the FDA as part of their NDA submission.

To the extent that the failure to warn claims are premised on the adequacy of the label as approved by the FDA when the drug was first marketed in the United States, they are preempted. See 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i) (setting out FDA labeling requirements). As the FDA has explained,

> The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professional about the risks and benefits of the approved product to help ensure safe and effective use.

Requirements of Content and Format of Labeling, 71 Fed. Reg. at 3934.

Because the complaint focuses almost exclusively on the ARISTOTLE study, it does not appear to be premised on any information that was "known or scientifically knowable" at the time of manufacture and distribution that might constitute "newly acquired information" under the CBE regulation. As discussed earlier, federal law expressly forbids a manufacturer

from changing its label after the label has received FDA approval unless such changes are made pursuant to the CBE regulation. The CBE regulation, in turn, requires that the "newly acquired information" be of a "different type or greater severity or frequency than previously included in submissions to [the] FDA." 21 C.F.R. § 314.3(b). Here, the complaint does not allege that the defendants were in possession of "newly acquired information" such that they could, pursuant to the CBE regulation, act independently of the FDA to update the Eliquis label with any of the fourteen categories of additional or improved warnings listed in the complaint.

The only potential reference in the complaint to "newly acquired information" is the following paragraph:

> Before and after marketing Eliquis, Defendants became aware of many reports of serious hemorrhaging in users of its drugs, both as reported to the FDA and to it directly. Yet Defendants have never disclosed to the medical profession or patients what the incidence of such adverse reactions are.

(Emphasis supplied.) This threadbare allegation fails to identify information that might constitute "newly acquired information, including whether that information, for example, revealed risks of a "different type" or "greater severity or frequency" than the information revealed to the FDA at the time of approval. See 21 C.F.R. § 314.3; see also id. § 314.70(c)(6)(iii). Thus, any claim against the

defendants for failure to warn under either a strict liability or negligence theory is dismissed, with leave to amend.

2. The Court Declines to Rule that the Eliquis Label Is Adequate as a Matter of Law.

The Court declines to rule on the adequacy of the Eliquis label before the plaintiffs have an opportunity to amend their complaint. Because some or even all of the failure to warn claims may be preempted, it would be premature to address whether the complaint has adequately pleaded a deficiency in the warnings given to physicians through the Eliquis label. Carlin, 13 Cal. 4th at 1116.

B. Design Defect

A design defect occurs where a product fails to perform "as safely as an ordinary consumer would expect when used in an intended and reasonably foreseeable manner," or if, on balance, "the risk of danger inherent in the design," outweighs "the benefits of the challenged design." Anderson, 53 Cal. 3d at 995. Under California law, a drug manufacturer may be held liable for an alleged design defect only when the plaintiff establishes that the manufacturer was negligent in designing the drug. A manufacturer may not be held strictly liable for a design defect. See Brown v. Superior Court, 44 Cal. 3d 1049, 1061 (1988) ("[A] drug manufacturer's liability for a

defectively designed drug should not be measured by the standards of strict liability."). Because the plaintiffs' strict liability design defect claim is barred by California law, it is dismissed with prejudice.

The defendants move to dismiss the negligent design defect claim on the grounds that it is preempted and inadequately pled. The complaint alleges that Eliquis was "defective in design or formulation in that, when it left the hands of the manufacturer and suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Eliquis ... and it was more dangerous than an ordinary consumer would expect."

The plaintiffs' negligent design defect claim is preempted. It asserts that the defendants had a pre-approval duty to submit a differently designed drug for FDA approval. To imagine such a pre-approval duty exists, the Court would have to speculate that had the defendants designed Eliquis differently, the FDA would have approved the alternate design; that Mr. Utts would have been prescribed this alternately designed Eliquis; and that this alternate design would not have caused Mr. Utts to suffer severe internal bleeding. Moreover, in order to assert preemption, the defendants "would be required continually to prove the counterfactual conduct of the FDA and brand-name manufacturer." Mensing, 564 U.S. at 623. This is precisely the type of "Mouse Trap" game the Supreme Court disavowed in Mensing. See id. at

619. "[T]he Supremacy Clause [does not] contemplate[] th[is] sort of contingent supremacy," nor should courts "strain to find ways to reconcile federal law with seemingly conflicting state law." Id. at 622-23.

The plaintiffs' negligent design defect claim fails for another reason as well. Insofar as the plaintiffs' design defect claim suggests that the defendants should never have sold the FDA-approved formulation of Eliquis, such claims have been explicitly repudiated by the Supreme Court. In Bartlett, the Supreme Court rejected an argument that a drug manufacturer "should simply have pulled [the drug] from the market in order to comply with both state and federal law." 133 S. Ct. at 2470. This "stop-selling" rationale is "incompatible with [the Court's] preemption jurisprudence," which "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." Id. at 2477.

Leave to amend is inappropriate for this claim. The complaint's allegations of harm due to the design defect go to the nature of the composition of the drug. The defendants had no ability to alter that composition without prior approval of the FDA. See 21 C.F.R. § 314.70(b)(2)(i) (providing that changes in the "qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the

specifications provided in the approved NDA" require supplemental submission and approval prior to distribution of the product made using the change). In sum, plaintiffs' design defect claims are dismissed with prejudice, without leave to amend.

C. Manufacturing Defect

A manufacturing defect is actionable under California law when the product "comes off the assembly line in a substandard condition: in some way it differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." Finn v. G.D. Searle & Co., 35 Cal. 3d 691, 715 (1984) (citation omitted). If a product meets the design specifications applicable at the time of manufacture, there is no manufacturing defect. In re Coordinated Latex Glove Litig., 121 Cal. Rptr. 2d 301, 315 (Cal. Ct. App. 2002).

The defendants move to dismiss the manufacturing defect claim as inadequately pled. The complaint alleges that Eliquis was "defective at the time of [its] manufacture," insofar as "the products differed from the Defendants' intended result and intended design and specifications, and from other ostensibly identical units of the same product line."

The motion to dismiss is granted, with leave to amend. The complaint fails to identify or explain how the product ingested by Mr. Utts either deviated from the defendants' intended result/design or from other seemingly identical product models. A bare allegation that the product had a manufacturing defect is too conclusory to plead a plausible claim or give the defendants fair notice.

V. Breach of Express and Implied Warranties

In order to plead a cause of action for breach of express warranty under California law, the plaintiff must allege: (1) the exact terms of the warranty; (2) the plaintiff's reasonable reliance thereon; and (3) a breach of that warranty which proximately caused plaintiff's injury. Williams v. Beechnut Nutrition Corp., 229 Cal. Rptr. 605, 608 (Cal. Ct. App. 1986). To maintain a claim for breach of implied warranty, a plaintiff must allege (1) that he intended to use the product for a particular purpose; (2) that the defendant had reason to know of this purpose; (3) that the plaintiff relied on defendant's skill or judgment to provide a product suitable for this purpose; (4) that the defendant had reason to know that buyers relied on its skill or judgment; (5) that the product was unfit for the purpose for which it was purchased; and (6) that it subsequently damaged the plaintiff. Keith v.

Buchanan, 220 Cal. Rptr. 392, 399 (Cal. Ct. App. 1985). In the context of prescription drugs, the warnings relevant to any breach of warranty claim are those "directed to the physician rather than the patient." Carlin, 13 Cal. 4th at 1118.

Breach of warranty claims may be maintained against a manufacturer of prescription drugs on a strict liability basis only when the manufacturer ignores known or knowable defects. As the California Supreme Court has explained,

> a manufacturer of prescription drugs is not strictly liable for injuries caused by such a defect that is neither known nor knowable at the time the drug is distributed. To hold nevertheless that the manufacturer's representation, express or implied, that a drug may be prescribed for a particular condition amounts to a warranty that it is "fit" for and will accomplish the purpose for which it is prescribed, and to allow an action for personal injury for the breach of such warranties, would obviously be incompatible with our determination regarding the scope of a drug manufacturer's liability for product defects.

Brown, 44 Cal. 3d at 1072 (citation omitted).

Finally, while privity of contract is ordinarily a prerequisite for recovery on a theory of breach of implied warranties of fitness and merchantability, Blanco v. Baxter Healthcare Corp., 70 Cal. Rptr. 3d 566, 582 (Cal. Ct. App. 2008), California recognizes an exception to the privity requirement for cases involving drugs. See Chavez

v. Glock, Inc., 144 Cal. Rptr. 3d 326, 353 (Cal. Ct. App. 2012).

The defendants argue that both the express and implied warranty claims are inadequately pled.[9] The complaint alleges that the defendants expressly warranted to Mr. Utts, his physicians, and the FDA that Eliquis was, inter alia, "safe and well accepted by users," "safe and fit for use of the purposes intended," of "merchantable quality," and that it "did not produce any dangerous side effects in excess of those risks associated with other forms of treatment." Because the drug was "defective," the defendants breached these express warranties. The complaint does not identify the express warranties on which this claim relies, including whether they appeared in the labeling and package inserts for the drug, which were approved by the FDA, whether they appeared in an advertising campaign for the drug, or how the particular warranty was breached. The plaintiffs will be given an opportunity to amend.

The complaint alleges that the defendants also impliedly warranted to the FDA, healthcare providers, and

[9] Because the warranty claims are so vaguely pleaded, it is impossible to know whether they may be preempted in whole or in part.

consumers that the drug was of merchantable quality and safe and fit for the ordinary purpose for which it was to be used. According to the complaint, because the drug was inherently dangerous, unsafe and defective, the defendants breached these implied warranties when they placed Eliquis into the stream of commerce. Given the breadth of this allegation, the plaintiffs appear to be challenging through their implied warranty claim the FDA's approval of Eliquis for sale to consumers. Many prescription drugs are inherently dangerous, which is why the FDCA imposes on manufacturers the duty to submit the drug to the FDA approval process before the drug may be prescribed by physicians and sold by pharmacists to patients. As with the express warranty claim, the plaintiffs are given leave to amend to provide fair notice of the basis for their claim.

VI. Fraud Causes of Action

The elements of fraud under California law are: (1) the defendant made a false representation; (2) the defendant knew the representation was false at the time it was made; (3) in making the representation, the defendant intended to deceive the plaintiff; (4) the plaintiff justifiably relied on the representation; and (5) the plaintiff suffered resulting damages. Lazar v. Superior

Court, 12 Cal. 4th 631, 638 (1996). The elements of negligent misrepresentation mirror those of fraud except for the second element, which for negligent misrepresentation is that the defendant made the representation "without reasonable ground for believing it to be true." West v. JPMorgan Chase Bank, N.A., 154 Cal. Rptr. 3d 285, 295 (Cal. Ct. App. 2013).

The elements of an action for fraudulent concealment are: (1) the defendant concealed or suppressed a material fact; (2) the defendant had a duty to disclose the fact to the plaintiff; (3) the defendant intentionally concealed the fact with the intent to defraud the plaintiff; (4) the plaintiff was unaware of the fact and would not have acted as he did if he had known of the concealed fact; and (5) as a result of the concealment of the fact, the plaintiff sustained damage. Knox v. Dean, 140 Cal. Rptr. 3d 569, 583 (Cal. Ct. App. 2012).

It is well established that a claim premised on a drug manufacturer's failure to provide data to the FDA is preempted. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001). In Buckman, the Supreme Court concluded that such claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." Id. at 350. The Court reasoned that allowing

state law fraud-on-the-FDA claims would "dramatically increase the burdens" facing potential drug applicants by causing applicants "to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." Id. at 350-51. The Buckman Court emphasized that "the relationship between a federal agency and the entity it regulates is inherently federal in character." Id. at 347. Accordingly, the FDA is empowered to investigate suspected fraud, receives citizens' reports of wrongdoing, and may bring court actions to respond to suspected fraud. Id. at 349 (citing statutory authority).

The defendants move to dismiss these claims on the grounds of preemption and failure to plead the claims with sufficient specificity. The parties agree that the plaintiffs' fraud, negligent misrepresentation, and fraudulent concealment claims all sound in fraud and are therefore subject to the heightened pleading standards of Rule 9(b).

These three claims assert that the defendants misrepresented the safety of Eliquis to the FDA, healthcare providers, and the plaintiff. The complaint asserts that the defendants knew from their research and testing that they were disseminating false information about the drug's safety and efficacy.

To the extent that these three claims are premised on the interaction between the defendants and the FDA, then they are preempted and dismissed with prejudice. To the extent that these claims seek to reach any other statements or conduct by the defendants, they must be dismissed for failure to meet Rule 9(b)'s pleading standards. For example, the plaintiffs fail to identify the statements or concealed information at issue, when such statements were made (or omitted), by whom, and through what channels. Accordingly, the defendants' motion to dismiss the three fraud claims is granted, with leave to amend.

VII. Consumer Protection Law

The complaint alleges a violation of New York consumer protection laws. The defendants seek to dismiss this claim on the ground that the plaintiffs, both California residents, lack standing to bring a consumer protection claim under New York law. The plaintiffs, in turn, request that they be granted leave to amend this claim should the Court choose to apply California law. Accordingly, the defendants' motion to dismiss the plaintiffs' New York consumer protection law claim is granted, with leave to amend.

VIII. Loss of Consortium

Because at least some of Mr. Utts' causes of action may be repleaded, the defendants' motion to dismiss the loss of consortium claim is denied.

IX. Punitive Damages

The defendants seek to dismiss the plaintiffs' demand for punitive damages. California Civil Code § 3294 provides that a plaintiff may seek exemplary damages in a non-contract claim "where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice." Because the plaintiffs have been given leave to amend some of their claims, it is premature to decide whether the claim for punitive damages should be stricken.

CONCLUSION

The defendants' October 5 motion to dismiss is granted in part. The design defect claims are dismissed with prejudice. The plaintiffs are given leave to amend their remaining claims. A separate scheduling order accompanies this Opinion.

Dated: New York, New York
December 23, 2016

DENISE COTE
United States District Judge